K132481

DEC 27 2013

510(K) SUMMARY

This summary document has been prepared in accordance with section 21 CFR 807.92(c).

The submitter of the 510(k) is:

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Date Summary Prepared: December 23, 2013

1. Subject Device:

Trade Name:	Easy-Load Lens Delivery System
Common Name:	Intraocular lens Guide
Classification Name:	21 CFR 886.4300

2. Predicate Device:

K970727, MPORT Foldable Lens Placement System

3. Device Description:

The Easy-Load Lens Delivery System is used for folding and delivering a Bausch + Lomb three-piece silicone IOL into the eye. An IOL is placed into the loading area and the drawer is closed. This compresses the IOL. The plunger is advanced until it stops at a detent position. The distal end is filled with viscoelastic or balanced salt solution and placed through an incision into the eye. The haptic puller is used to place the leading haptic in the correct loading position. Once the tip is in the eye, the plunger is advanced until the lens is fully expressed into the capsular bag.

4. Indications for Use:

The Easy-Load Lens Delivery System is indicated for the folding and injection of Bausch + Lomb intraocular lenses identifying the Easy-Load Lens Delivery System in their approved labeling.

5. Brief Summary of Nonclinical Tests and Results:

The Easy-Load Lens Delivery System was evaluated via biocompatibility and bench testing. Biocompatibility testing was performed on the new Easy-Load Lens Delivery System materials and they were found to be biocompatible. Bench testing (surface and bulk homogeneity of delivered IOLs, delivery outcome, and injector visual inspection) was performed on Easy-Load Lens Delivery Systems with the new materials. All the nonclinical tests met the acceptance criteria.

6. Comparative Analysis

A table comparing the proposed device to the predicate devices is provided below.

Table 6-1: Comparison of Predicate Device to the Proposed Easy-Load Lens Delivery System

Characteristic	Predicate K970727 MPORT Foldable Lens Placement System	Easy-Load Lens Delivery System (Proposed Device)
Indications for use	The MPORT Foldable Lens Placement System is a Class I device indicated for compressing and inserting a Soflex (formerly Chiroflex II) series multi-piece intraocular lens into the eye during small incision cataract surgery.	The Easy-Load Lens Delivery System is indicated for the folding and injection of Bausch + Lomb intraocular lenses identifying the Easy-Load Lens Delivery System in their approved labeling.
Contraindications	None	None
Materials	Body, drawer, haptic puller, plunger: polypropylene Spring: stainless steel	Body, drawer, haptic puller, plunger: polypropylene Spring: stainless steel
Is the product single use?	Single use	Single use
Is the product sterile?	Sterile	Sterile
How sterilized	Ethylene oxide	Ethylene oxide
Sterility assurance level	10^{-6}	10^{-6}
Shelf life	12 months	12 months

7. Conclusion

The Easy Load Lens Delivery System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 27, 2013

Bausch + Lomb
% Mr. Jason Smith
Manager, Global Regulatory Affairs
50 Technology Drive
Irvine, CA 92618

Re: K132481
Trade/Device Name: Easy-Load Lens Delivery System
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I (reserve)
Product Code: MSS
Dated: November 19, 2013
Received: November 20, 2013

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: Registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah L. Falls -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

5 Indications for Use Statement

510(k) Number (if known): 132481

Device Name: Easy-Load Lens Delivery System

Indications for Use:

The Easy-Load Lens Delivery System is indicated for the folding and injection of Bausch + Lomb intraocular lenses identifying the Easy-Load Lens Delivery System in their approved labeling.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susanna W. Jones -S
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